

K013049

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GENERAL DENTIST: PRACTICE RESTRICTED TO
CRANIOFACIAL PAIN & RELATED HEADACHE DISORDERS,
OROFACIAL PAIN & TEMPOROMANDIBULAR JOINT DISORDERS,
INTRAORAL APPLIANCE THERAPY FOR SNORING & RELATED BREATHING DISORDERS,
ORTHODONTICS

NOV 29 2001

Premarket Notification [510(k)] Summary

Contact Person: Dennis R. Bailey, DDS
Date Prepared: September 5, 2001
Name of the Device: NOrAD
Trade Name: NOrAD
Common Name: Mandibular repositioning appliance (device)
Classification Name: Device, Anti-Snoring

Substantial Equivalence is being made to other "boil and bite" or "boil and fit" devices, specifically the Silencer Custom and the Therasnore, which are advocated for the management of snoring.

Description of the Device: This device has a hard outer component with heat sensitive material contained within that component. The heat sensitive material is softened and is what fits the appliance to the patient's teeth for securing the appliance in place. Hooks for conventional Orthodontic elastics exist on the outer component for the purpose of attaching the elastics to prevent the mandible from retruding. The upper component has two (2) hooks and the lower component has one (1) hook. This allows for various methods of elastic placement depending on the need(s) of the patient. There is ramping on both the upper and the lower to facilitate and guide the mandible forward when the

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patient is in occlusion. These ramps also provide a posterior stop for support of the mandible. The appliance also provides for full coverage of the dentition to prevent any tooth movement or occlusal changes. The teeth at the anterior of the appliance allow for indexing of the appliance at a position most acceptable to the patient during wear and allows the patient to determine the most effective jaw position for repositioning dependent on sleep position. The teeth index in such a way to allow for freedom of movement of the jaw during sleep while remaining in an indexed position.

Intended Use: This device is intended for the control, reduction and management of snoring, primarily nocturnal, allowing for quieter sleep with less sleep fragmentation. Sleep fragmentation is equivalent to sleep disruption and has been shown to be responsible for daytime hypersomnolence.

Technologic Characteristics: Compared to the Silencer Custom and the Therasnore the NOOrAD appliance does not hold or lock the jaw into a set position while also repositioning the mandible. The NOOrAD allows for free movement both vertically as well as laterally and to some degree horizontally. This allows the patient the ability to move the jaw during sleep without inducing increased muscle activity.

Substantial Equivalence is based on non-clinical data as it relates to the historical significance of oral devices that reposition the jaw and reduce or manage snoring. Pancer et al described this in an article published in the journal CHEST in 1998, where they concluded that mandibular repositioning

appliances were 95% successful in reducing and/or controlling snoring. In addition the American Academy of Sleep Medicine (formerly the American Sleep Disorders Association) published in 1995 their Standards of Practice and Guidelines which demonstrated that oral appliances were effective in the management of snoring.

Based on clinical data, repeatedly demonstrated in a variety of articles that looked at oral appliances and their use for the treatment of snoring, oral appliance therapy is an effective means by which snoring can be managed. This effectiveness is embraced from a variety of aspects including safety, convenience and cost.

In conclusion, a number of studies have shown improvement of the airway utilizing imaging associated with the use of oral appliances (also referred to as Oral Airway Dilators), which aids in the management and reduction of snoring.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NOV 29 2001

Dr. Dennis R. Bailey
Dennis R. Bailey, DDS
7901 East Belleview Avenue, Suite
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Re: K013049

Trade/Device Name: Norad, Nocturnal Oral Airway Dilator Appliance
Regulation Number: None
Regulation Name: Intra-Oral Mandibular Repositioner
Regulatory Class: Unclassified
Product Code: LRK
Dated: September 7, 2001
Received: September 11, 2001

Dear Dr. Bailey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

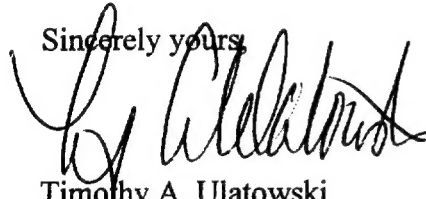
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K013049

Device Name: NorAD

Indications For Use:

The NOrAD device is indicated for use in patients who are snorers and wish to reduce or otherwise manage their snoring while sleeping.

The device is to be used with individuals in whom it has been determined that they are primary snorers and are not at risk for sleep apnea. In many instances these individuals may have had a sleep study and have been found to have a Respiratory Disturbance Index (RDI) below the level that necessitates a diagnosis for sleep apnea. They may also be individuals who are snorers and whose physician has determined that they are not candidates for a sleep study and may proceed with management of their snoring utilizing this device. Many times this decision will have been achieved after consultation has occurred between the dentist and their physician.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley Runya
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013049

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)